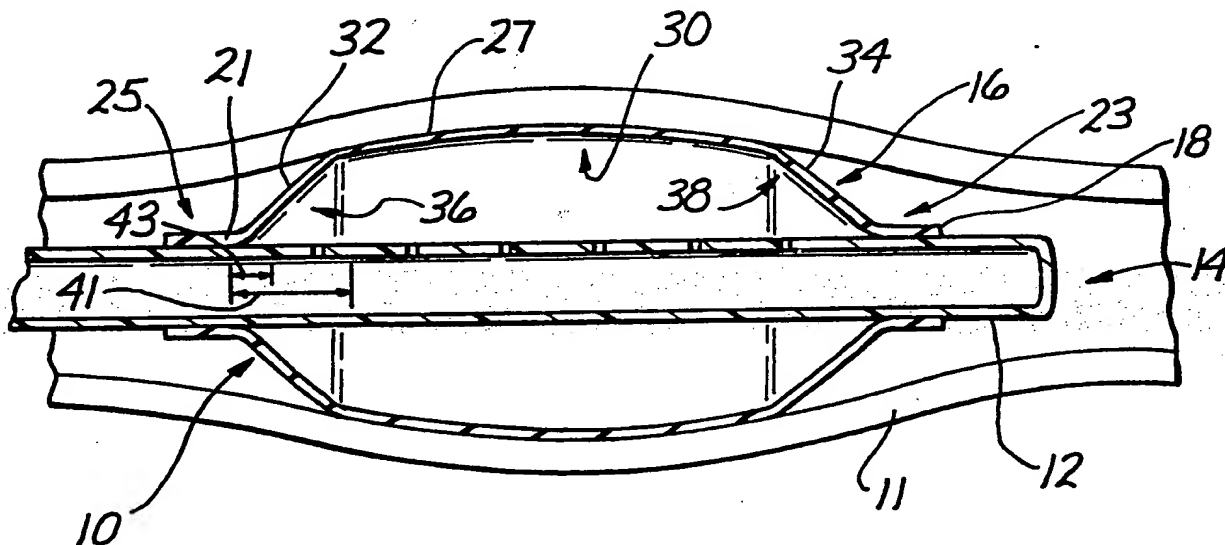




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁵ : A61M 29/00	A1	(11) International Publication Number: WO 92/11892 (43) International Publication Date: 23 July 1992 (23.07.92)
<p>(21) International Application Number: PCT/US92/00307</p> <p>(22) International Filing Date: 7 January 1992 (07.01.92)</p> <p>(30) Priority data: 639,672 8 January 1991 (08.01.91) US</p> <p>(71) Applicant: APPLIED MEDICAL RESOURCES, INC. [US/US]; 26051 Merit Circle, #104, Laguna Hills, CA 92653 (US).</p> <p>(72) Inventors: ALIAHMAD, Wassim ; 5 Shadwell, Irvine, CA 92720 (US). HILAL, Said, S. ; 25291 Spindlewood, Laguna Niguel, CA 92677 (US). HILAL, Nabil ; 24576 Vanessa Drive, Mission Viejo, CA 92691 (US).</p>		<p>(74) Agent: MYERS, Richard, L.; 26051 Merit Circle, # 104, Laguna Hills, CA 92653 (US).</p> <p>(81) Designated States: AT (European patent), BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), MC (European patent), NL (European patent), SE (European patent).</p> <p>Published With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</p>

(54) Title: LOW PROFILE BALLOON CATHETER AND METHOD FOR MAKING SAME



(57) Abstract

A non-distensible balloon (16) is adapted to be disposed circumferentially on a tube (12) having an elongate axis and to be compressed against the tube (12) to achieve a low profile. The balloon (16) includes an end wall (21), a central wall (27), and a transition wall (32) defined by a height transition region having a first axial length and defined by a thickness transition region having a second axial length less than the first axial length. An associated method includes the step of reducing the average volume of material per unit axial length in the transition wall of the balloon relative to the average volume of material per unit axial length in either the end wall or central wall of the balloon.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT Austria
 AU Australia
 BB Barbados
 BE Belgium
 BF Burkina Faso
 BG Bulgaria
 BJ Benin
 BR Brazil
 CA Canada
 CF Central African Republic
 CG Congo
 CH Switzerland
 CI Côte d'Ivoire
 CM Cameroon
 CS Czechoslovakia
 DE Germany
 DK Denmark

ES Spain
 FI Finland
 FR France
 GA Gabon
 GB United Kingdom
 GN Guinea
 GR Greece
 HU Hungary
 IT Italy
 JP Japan
 KP Democratic People's Republic
 of Korea
 KR Republic of Korea
 LI Liechtenstein
 LK Sri Lanka
 LU Luxembourg
 MC Monaco

MG Madagascar
 ML Mali
 MN Mongolia
 MR Mauritania
 MW Malawi
 NL Netherlands
 NO Norway
 PL Poland
 RO Romania
 RU Russian Federation
 SD Sudan
 SE Sweden
 SN Senegal
 SU Soviet Union
 TD Chad
 TG Togo
 US United States of America

LOW PROFILE BALLOON CATHETER
AND METHOD FOR MAKING SAME

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates generally to surgical devices, and more specifically to nondistensible balloon catheters.

Description of Prior Art

Balloon catheters are used to dilate or occlude various body conduits, cavities and openings such as blood vessels and the urethra. This is normally accomplished with a catheter formed from an elongate cannula and an inflatable balloon disposed circumferentially of the cannula near the distal end of the catheter.

15

In accordance with a typical procedure, the catheter is provided with the balloon in a deflated or otherwise low profile state. With this configuration, the catheter is introduced into the body conduit and positioned with the balloon in the low profile state at the point of desired dilatation. At this point the balloon is inflated or otherwise expanded to a high profile state thereby radially stretching the walls of the conduit.

20

25

This procedure is particularly applicable in the case of blood vessels which are occluded by plaque. In such a procedure, the balloon in its low profile state is positioned in proximity to the plaque. At this point the balloon is inflated to press the plaque radially against

the walls of the blood vessel and thereby dilate or open the vessel to blood flow.

The procedure is also applicable for dilating large body conduits such as the gastrointestinal tract or the prostatic urethra. In the latter case, restrictions are common to men of older age where the prostate, which encircles the urethra, tends to grow inwardly thereby restricting the urethra passage. With the balloon in its low profile state, the catheter can be inserted into the urethra until the balloon is positioned in proximity to the restriction. At this point the balloon can be inflated to dilate the urethra and thereby increase the flow capacity of this conduit.

15

These dilatation catheters are typically characterized by nondistensible balloons which are formed from materials such as polyethylene that are relatively inflexible and therefore do not expand or distend significantly beyond a known dimension. This characteristic of non-distensibility is of particular advantage in order to insure that the vessel or conduit is not injured by overextension. Unfortunately, the relatively inflexible materials which produce the nondistensible characteristics, tend to inhibit the ability of the balloon to be rolled, compressed, collapsed, deflated or otherwise formed into a low profile state. Such a state is of particular interest in order that the catheter can be easily inserted into the vessel or conduit.

30

Nondistensible balloons are typically formed circumferentially and co-axially on the cannula. The balloons are characterized by two cylindrical end regions which are attached to the cannula, a cylindrical central region which is spaced from the cannula when the balloon is

35

inflated, and a pair of conical transition regions each extending from an associated end region outwardly to the central region.

5 With this configuration, the nondistensible balloons of the past have been blow molded from materials which are commonly provided in the configuration of a tube having a substantially constant wall thickness. In the blow molding process, the walls of the tube are expanded against the
10 inner surface of a mold which is provided with a shape desired for the balloon. Ends of the balloon remain at the initial diameter and thickness of the tube, while the central region of the balloon expands to the maximum diameter and minimum wall thickness of the balloon. It is
15 these walls in the central region, which may have a thickness reduced by a factor as much as 100, that dictate the strength of the balloon. Between the central region and each of the end regions of the balloon, one of the transition zones is characterized by a wall thickness which
20 varies from the original thickness of the wall of the tube to the reduced thickness of the wall of the central region.

When these nondistensible balloon catheters are initially inserted, it is of particular importance that the
25 balloon be rolled on the catheter tube to the smallest diameter in order to provide the catheter with the lowest profile possible. The rolling of the balloon has not been a problem in the end regions. Even though end walls contain the thickest wall section, they are fixed in close
30 proximity to the cannula and therefore maintain a low profile even when the balloon is inflated. Similarly, rolling the balloon on the cannula has not been a problem in the central region. Even though the walls in this region are disposed at the highest radial distance from the
35 cannula, the very thin walls in this region are adaptable

to being rolled into close compliance with the cannula. However, in the transition regions of the balloon, both the thickness of the wall and the radial displacement of the wall tend to create a problem. Although the transition
5 wall is thinner than that in the end region, it is disposed at a greater radial distance than the end wall. And although this radial distance is less than that of the central region, the wall thickness is greater and therefore more rigid than the central region.

10

When a nondistensible balloon of the past has been rolled onto a cannula, it has resulted in enlarged sections at each transition region, giving the rolled balloon the appearance of a dog bone. These enlarged transition
15 sections typically have diameters as much as 50% greater than those associated with either the central section or the end section of the rolled balloon. Furthermore they tend to form sharp corners which can severely damage the body conduit during both insertion and withdrawal of the
20 catheter.

With these deficiencies of the prior art, it is an object of the present invention to provide a balloon catheter wherein the balloon can be rolled or otherwise
25 compressed onto the catheter tube to a diameter which is substantially constant along the entire length of the rolled balloon.

SUMMARY OF THE INVENTION

30

In accordance with the present invention, a balloon catheter is provided wherein the balloon can be rolled on the catheter tube to a profile which is substantially constant in diameter along the length of the balloon.
35 Furthermore, there are no sharp points associated with this

low profile. As a result, the greatest diameter of the catheter with the balloon in its low profile state, is reduced by as much as 50% with substantially no sharp edges to damage the body conduit.

5

In one aspect of the invention, a nondistensible balloon is adapted to be rolled on a cannula having an elongate axis, in order to achieve a low profile. The balloon comprises an end wall disposed in an end region of the balloon and having a fixed circumferential relationship with the cannula. A central wall disposed in a central region of the balloon is displaced from the cannula when the balloon is inflated. A transition wall disposed between the end wall and the central wall includes a height transition region where the transition wall extends from the height of the end wall to the height of the central wall, and a thickness transition region where the transition wall extends from the thickness of the end wall to the thickness of the central wall. The axial length of the thickness transition zone is less than the axial length of the height transition zone.

In another aspect of the invention, a method for making a nondistensible balloon characterized by an end wall, central wall and transition wall, includes the step of providing a blow mold having an end wall surface, a central wall surface and a transition wall surface equivalent to the external shape desired for the respective end wall, central wall and transition wall when the balloon is inflated. The method further comprises the steps of inserting a tube of material into the mold and blow molding the material of the tube against the surface of the mold. Finally, the process calls for reducing the quantity of material per unit length in the transition wall to an amount less than the average volume of material per unit

length in either the end wall or the central wall of the balloon.

5 In other aspects of the invention, the traditional blow molding method is altered by providing the tube of material with a reduced wall thickness in those areas which correspond to the transition regions of the balloon. This automatically reduces the quantity of material and hence the thickness of the transition walls.

10

In another method, a balloon formed in accordance with the prior art is inserted into a funnel or mold which is configured to receive at least the transition wall of the balloon. This second mold is heated to increase the flexibility of the balloon in the transition region, and the balloon is stretched axially to thin the heated wall.

15

In still a further method, the blow mold is formed with recesses in the transition surface. In such a mold, the balloon is formed with projections in the transition region, which increase the surface area and therefore decrease the thickness of the transition walls.

20

25 These and other features and advantages of the invention will be more apparent with a description of preferred embodiments and reference to the associated drawings.

30

35

DESCRIPTION OF THE DRAWINGS

Fig. 1 is an axial cross-section view of one embodiment of a balloon catheter of the present invention, showing the catheter operatively disposed in a body conduit;

Fig. 2 is an axial cross-section view of a balloon associated with the prior art rolled onto a cannula and illustrating the dog bone profile associated with the prior art;

Fig. 3 is an axial cross-section view illustrating the low profile, rolled characteristics associated with the balloon of Fig. 1;

Fig. 4 illustrates a top plan view of a blow mold used in the prior art method for making the balloon illustrated in Fig. 2;

Fig. 4a is an axial cross-section view of blow mold tubing used in the prior art method;

Fig. 4b is an axial cross-section view of the tubing of Fig. 4a being heated in the prior art process;

Fig. 4c is an axial cross-section view of the tubing of Fig. 4 coaxially disposed in the mold of Fig. 4;

Fig. 4d illustrates the blow molding step in the process of the prior art;

Fig. 5 is an enlarged axial cross-section view of one quadrant of the balloon of the prior art illustrated in an inflated state;

Fig. 5a is a cross-sectional view taken along lines 5a-5a of Fig. 5;

Fig. 5b is an axial cross-section view taken along lines 5b-5b of Fig. 5;

Fig. 5c is an axial cross-section view taken along lines 5c-5c of Fig. 5;

Fig. 6 is an axial cross-section view of one quadrant of the balloon of Fig. 1 illustrated in an inflated state;

Fig. 6a is a cross-sectional view taken along lines 6a-6a of Fig. 6;

Fig. 6b is an axial cross-section view taken along lines 6b-6b of Fig. 6;

Fig. 6c is an axial cross-section view taken along lines 6c-6c of Fig 6;

Fig. 7 is an axial cross-section view similar to Fig. 6 of a further embodiment of the balloon associated with the present invention;

Fig. 7a is a cross-sectional view taken along lines 7a-7a of Fig 7;

Fig. 7b is an axial cross-section view taken along lines 7b-7b of Fig. 7;

Fig. 7c is an axial cross-section view taken along lines 7c-7c of Fig. 7;

Fig. 8 is an axial cross-section view of bump tubing used in a method of the present invention;

5 Fig. 8a is an axial cross-section view of the bump tubing of Fig. 8 inserted in a conventional blow mold associated with the present invention;

10 Fig. 8b is an axial cross-section view showing the molded balloon with a transition wall of substantially constant thickness;

Fig. 9 is an axial cross-section view of a second mold or funnel associated with a further method of the present invention;

15

Fig. 9a illustrates a balloon disposed in the funnel of Fig. 9, heated, and stretched in the transition region to form a transition wall of reduced thickness;

20 Fig. 10 is a top plan view of a blow mold associated with a further method of the present invention;

25 Fig. 10a is an axial cross-section view of the balloon disposed in the mold of Fig. 10, heated, and axially stretched in the transition regions to provide a transition wall of reduced thickness;

Fig. 11 is a top plan view of a mold associated with a further method of the present invention;

30

Fig. 12 is an axial cross-section view of a conventional balloon with a sleeve bonded to the central regions of the balloon; and

10

Fig. 13 is an axial cross-section view of two balloon portions wherein central regions of each balloon portion are overlapping and bonded to increase the thickness of the central wall of the balloon.

5

Description of Preferred Embodiments

10 A dilatation catheter is illustrated generally in Figure 1 and designated by the reference numeral 10. The catheter 10 is operatively disposed in a body conduit defined by walls 11, and includes an elongate cannula 12 having a distal end 14 and a proximal end (not shown).

15

The catheter 10 also includes a balloon 16 having a distal end wall 18 and a proximal end wall 21 disposed in respective end regions 23 and 25 of the balloon 16. A central wall 27 is disposed between the end walls 18 and 21 in a central region 30 of the balloon 16.

20

In this particular embodiment the end walls 18 and 21 are relatively thick and relatively small in diameter. This is in comparison to the central wall 27 of the balloon 16 which is relatively thin and relatively large in diameter.

25

A pair of transition walls 32 and 34, each having a generally conical configuration, are of particular interest to the present invention. The transition wall 32 is disposed in a proximal transition region 36 between the end region 25 and the central region 30. The transition wall 34 is disposed in a distal transition region 38 between the end region 23 and the central region 30 of the balloon.

35

Two separate transitions occur to the walls 32, 34 in each of the transition regions 36, 38. First, the walls 32, 34 are each characterized by a transition in height from the height of the respective end walls 18, 21 to the height of the central wall 27. This transition region will be referred to as the height transition region 41. Second, in the transition regions 36, 38 the walls 32, 34 respectively, undergo a transition from their greatest thickness in proximity to the end region 25, 23 respectively, to their least thickness in proximity to the central region 30. This transition region is referred to as the thickness transition region 43. It is the relative axial length of the two regions of transition, the height transition region 41 and the thickness transition 43, which are of particular interest in this case.

In accordance with the present invention, the thickness transition region 43 has a shorter axial dimension than does the height transition region 41. This occurs because the thickness of the end wall 21 thins to a dimension generally equivalent to the thickness of the central wall 27 over a relatively short distance along the transition wall 32. It is particularly desirable that this thickness transition region 43 be positioned in close proximity to the end wall 21 so that any substantial wall thickness associated with the region 43 is closely spaced to the outer surface of the cannula 12.

As will be discussed in greater detail below, the balloons of the prior art have a thickness transition region 43 which is generally equivalent in axial length to the height transition region 41. In other words, the thickness of the transition wall 32 gradually decreases over the entire axial distance between the end region 25 and the central region 30. While this does not adversely

affect the balloon in its inflated, high profile state, it has a dramatic affect on the rolled, low profile state of the balloon as illustrated in Figure 2. With the relative thickness of the transition wall spaced even a short radial distance from the cannula 12, the balloon 10 in its rolled configuration tends to have an undesirable dog bone shape. Thus in the low profile state, in the low profile state, enlargements occur at both of the transition regions 36 and 38 with the balloon of the prior art. It is in these regions that the respective walls 32 and 34 are too thick and too far displaced from the cannula 12 to adequately comply to the cannula in the rolled state.

By thinning the walls 32 and 34 of the transition regions 36, 38 respectively, the walls of the balloon 16 are either thick in proximity to the cannula 12 or thin at any substantial radial distance from the cannula 12. It is in this manner that the balloon of Figure 1 in the rolled configuration achieves a low profile state as illustrated in Figure 3.

An understanding of the wall thickness associated with the transition zones 36, 38 and its effect on the rolled configuration of the balloon 10 will be better understood with reference to a typical blow molding process used to manufacture the balloon of the prior art. Figure 4 and Figures 4a-4d illustrate steps in a blow molding process of the prior art; however, some of these steps also apply to the methods associated with the present invention.

In the plan view of Figure 4, a blow mold 50 is illustrated with an inner mold surface 52 which defines a cavity 54 having the shape desired for the external surface of the balloon 16. Thus the surface 52 includes end surfaces 56, 58 which correspond to the end regions 23, 25

respectively, a central surface 61 which corresponds to the central region 30, and transition surfaces 63, 65 which correspond to the transition regions 36, 38 respectively.

5 In accordance with this process of the prior art, material is provided in the form of a tube 67 which has a generally cylindrical configuration and a relatively constant wall thickness as illustrated in Figure 4a. The tube 67 is heated, for example in a conventional oven 69,
10 to provide the tube 67 with a generally limp, pliable configuration. In this state, the tube 67 is inserted into the mold 50 and stretched axially as shown by the arrows 70 in Figure 4c. This axial stretching tends to align the tube 67 coaxially with the cavity 54 of the mold 50.

15

 At this point in the process, one end of the tube 67 is sealed by a clamp shown generally at 72 in Figure 4d. The other end of the tube 67 is inflated by a fluid, such as air, provided by a compressor 74. This air is blown
20 into the heated tube 67 stretching the walls of the tube 67 until they contact the surface 52 of the mold 50. Upon contact, the walls of the balloon 16 are cooled by the mold 50 and frozen in their expanded state.

25 It will be apparent with reference to Figure 4d that the volume of material per unit length provide by the tube 67 will also be equivalent to the volume of material per unit length of the walls forming the balloon 16. Where the central wall 27 is greatly spaced from the axis of the
30 balloon, this constant volume will necessarily require a relatively thin central wall 27. Where there is substantially no radial displacement of the tube 67, for example in the end region 23, 25 the thickness of the respective end walls 18, 21 will be substantially the same
35 as the thickness as the walls of the tube 67. Along the

transition walls 32, 34, the result achieved with the formation of the end walls 18, 21 gives way to the result achieved with the formation of the central wall 27. Thus the greater the radial displacement of the walls of the tube 67, the less the thickness of the resulting wall of the balloon 16.

In a further description of the invention, focus will be directed primarily to the transition region 36 illustrated in the upper left hand corner of the balloon 16 in Figure 1. However, the comments will apply equally as well to the quadrant of the balloon 16 in the lower left hand corner of Figure 1. Comments may also apply to transition region 38 illustrated on the right hand side of the balloon 16 of Figure 1.

The transition region, such as the region 36, is illustrated for a balloon of the prior art in the enlarged view of Figure 5. In this view it is apparent that the thickness transition zone 43 is substantially equivalent in axial dimension to the thickness transition zone 41. Because there is substantial thickness of the wall 32 in the transition zone 36 at substantial radial dimensions from the cannula 12, the balloon 16 in the rolled configuration has the dog bone profile illustrated in Figure 2. The thickness of the walls 21, 32 and 27 is measured and discussed with respect to their dimension in a radial plane as illustrated by the thickness "t" in Figure 5.

30

As long as the volume of material per unit axial length remains constant along the walls of the balloon 16, as is the case with the balloons of the prior art, a relationship can be established based on the thickness "t" at any two locations along the balloon walls. Figures 5a,

35

5b and 5c show radial cross-sections of the prior art balloon in Figure 5 taken along the lines 5a, 5b and 5c respectively. Referring to Figure 5b, the transition wall 32 has a thickness t_1 at a point "1" in Figure 5. This thickness t_1 is equivalent to the difference between the inner radius r_1 and the outer radius R_1 of the wall 32.

Similarly in Figure 5c, the wall of the balloon 16 has a thickness t_2 at a point "2" between the central region 30 and the transition region 36. This thickness t_2 is equivalent to the difference between the inner radius r_2 and the outer radius R_2 of the wall 32. If the volume per unit length of material in the walls 21, 32 and 27 is equivalent, as is the case with the balloons of the prior art, then the shaded areas in Figures 5b and 5c will be equivalent in size. It follows that the thickness of the wall at any point, such as the point 1, can be determined given the radii r_1 and R_1 at point 1, the thickness at any point 2 and the associated radii r_2 and R_2 at point 2. It follows that this relationship is established by the following Formula I:

$$t_1 = t_2 \left(\frac{r_2 + R_2}{r_1 + R_1} \right)$$

This relationship has existed in the prior art and has given rise to the noncompliant, dog bone shape of the balloon 16 in its low profile configuration as illustrated in Figure 2. In accordance with the present invention, the thickness t_1 will be given by the following Formula II:

$$t_1 < t_2 \left(\frac{r_2 + R_2}{r_1 + R_1} \right)$$

This is illustrated in the embodiment of Figure 6 where the thickness t_1 at the point 1 is substantially equivalent to the thickness t_2 at the point 2. The conditions of Formula II will be met since the sum of $r_1 + R_1$ is less than the sum of $r_2 + R_2$. This can be appreciated by merely noticing that the shaded area in Figure 6b has a smaller area than does the shaded area in Figure 6c.

In particular embodiments of the invention, it is desirable that the axial length of the thickness transition region 43 be maintained at less than one-half the axial length of the height transition region 41. In the most preferred embodiment, the full transition in thickness from the thickest wall 21 to the thinnest wall 27 occurs within only one-fourth of the axial distance along the height transition region 41. Of course, the maximum advantage is achieved where the wall 32 is consistently thin throughout the entire height transition region 41. And in an ideal case, the end wall 21, the transition wall 32, and central wall 27 all have the same thinness. Even in this case the strength of the balloon is still determined by the thickness of the central wall 27.

This reduced wall thickness of the transition region 36 can be provided in an embodiment where the walls 32 are provided with an increased area so that they are automatically thinned due to the scarcity of the material. In the embodiment of Figure 7, the increased area in the transition region 36 is provided in the form of projections 81. By adding these projections 81, the area of the balloon in the region 36 is increased so that the thickness

17

of the wall 32 is substantially equivalent to the wall 27. In such an embodiment, the thin walls in the transition region 36 are as compliant as the walls 27 in the central region 30. This facilitates rolling the balloon into a low profile state as illustrated in Figure 3.

The balloons of the present invention also can be made in accordance with a preferred method shown by the steps illustrated in Figures 8-8b. Thus the process of Figure 4 can be revised in the step illustrated in Figure 4a by providing the tube 67 in a configuration illustrated in Figure 8. In this case, the tube 67 has walls of generally constant thickness in a pair of end zones 90 and 92 which are associated with the end regions 23 and 25 respectively of the balloon 16. The wall of the tube 67 has a greater cross sectional area in a central zone 94 which is associated with the central region 30 of the balloon 16. Between each of the zones 90, 92 and the central zone 94, a pair of transition zones 96, 98 respectively, are provided which supply the material associated with the transition regions 36 and 38 of the balloon 16.

The walls of the tube 67 in the transition zones 96, 98 have reduced cross-sectional area relative to the walls in the central zone 94. When the tube of Figure 8 is inserted into the mold 50 as illustrated in Figure 8a, the reduced material available in the transition zones 96, 98 automatically produces a balloon 16 with transition regions 36, 38 of reduced thickness. In this manner, the balloon of Figure 1 can be produced in accordance with the method steps illustrated in Figures 8 - 8b.

Referring to Figures 9 and 9a, it will be apparent that all of the steps associated with Figures 4-4d which produce the prior art balloon of Figure 5, are equally

applicable to an improved process wherein a second mold is provided in the shape of a funnel 101. The funnel 101 can be formed from stainless steel or other suitable material and surrounded by induction coils 103. An inner surface
5 105 of the funnel 101 is provided with the shape desired for the exterior surface of the balloon 16 particularly in the transition region 36.

In this extended process the induction coils 103 can
10 be energized by a signal from a radiofrequency generator 107. This radiofrequency energy is inductively coupled to the funnel 101 to heat the interior surface 105. Inserting the balloon 16 of the prior art into the funnel 101, as illustrated in Figure 9, heats the transition zone 36.
15 When axial tension is applied to the end wall 21 of the balloon 16, as illustrated by the arrow 109, the heated transition wall thins to the reduced thickness illustrated in Figure 6.

20 In a similar method illustrated in Figures 10 and 10a, the mold 50 is provided with a pair of end sections 110 and 112, a central section 114, and a pair of transition sections 116 and 118. In this case, the material forming the transition sections 116, 118 and the end sections 110
25 and 112, is preferably heatconductive, such as metallic, while the material forming the central section 114, is preferably non-heatconductive such as plastic.

With the balloon 16 disposed in the mold 50, the
30 entire mold can be heated by a heater 119 to increase the temperature of the metallic sections 116, 118, 110 and 112. The plastic section 114, however, will not easily transmit the heat so the central region 30 of the balloon 16 remains relatively cool. By axially stretching the balloon 16
35 under these conditions, the heated material in the

transition regions 36, 38 and the end regions 110, 112 will be thinned to provide the balloon 16 with the configuration illustrated in Figure 8b.

5 In still a further method of the present invention the mold 50 illustrated in Figure 4 can be modified by providing recesses 125 in the transition surfaces 63 and 65. Using the remainder of the steps illustrated in Figures 4a-4d will produce a balloon 16 having the
10 configuration illustrated in Figure 7. With the reduced wall thickness provided by the projections 81, the balloon 16 can be rolled to a low profile state as illustrated in Figure 3.

15 As previously discussed, the strength of the balloon 16 is dictated primarily by the wall thickness in the central region 30 while the problems associated with the low profile are dictated primarily by the wall thickness in the transition zones 36, 38. The prior art has not been
20 able to develop reduced wall thicknesses in the transition zones 36 and 38 which are sufficiently thin to avoid the dog bone effect without sacrificing strength in the central region 30.

25 In order to reduce wall thicknesses in the transition regions of the prior art, it has required that the wall thicknesses in the central region 30 also be reduced below the thickness required for minimum strength. However, it will now be possible in accordance with the concept of the
30 present invention to form just such a balloon with reduced wall thicknesses in the transition regions 36 and 38, and then to reinforce the central region 30, for example with a sleeve 130 as illustrated in Figure 12. Bonding the sleeve 130 onto the central wall 27 will increase the
35 strength of this critical central region 30 without

otherwise increasing the thickness of the walls in the transition regions 36 and 38.

It is also within the scope of the present invention to provide two separate wall sections each formed in accordance with the method of Figure 4. For example, in Figure 13, a wall section 136 is illustrated to include the end wall 21, the transition wall 32 and a central wall 27a. Similarly, a second balloon section 138 includes the end wall 18, the transition wall 34 and a central wall 27b. The central wall 27b can be inserted into the central wall 27a and bonded in this position. The resulting wall in the central region 30 will have a double, reinforced thickness without increasing the thickness of the transition walls 32 or 34.

Although the invention has been described with reference to preferred embodiments and methods, it will be apparent that the balloon and catheter associated with the present invention can be otherwise embodied and manufactured. For example, in all of the foregoing examples requiring a blow mold, the mold can be entirely eliminated in which case the balloon is free formed. In the absence of a mold, control over the ultimate shape of the balloon is somewhat restricted. Nevertheless, the concepts disclosed herein for reducing the wall thicknesses particularly in the transition region of the balloon are equally applicable. Due to these variations in the concept, one should not refer merely to the drawings or the particular embodiments discussed. Rather, the scope of the invention should be ascertained only with reference to the following claims.

CLAIMS

1. A non-distensible balloon adapted to be disposed circumferentially on a tube having an elongate axis, and adapted to be rolled on the tube to achieve a low profile, the balloon comprising:

5 an end wall disposed in an end region of the balloon and in a fixed circumferential relationship with the tube;

a central wall disposed in a central region of the balloon and in a displaced relationship with the tube when the balloon is inflated;

10 a transition wall disposed between the end wall and the central wall of the balloon;

first portions of the balloon disposed in the transition wall and having a thickness t_1 , an inside radius r_1 , and an outside radius R_1 ;

15 second portions of the balloon disposed in one of the end wall, central wall and the transition wall, and having a thickness t_2 , an inside radius r_2 and an outside radius R_2 ; and

20 the thickness t_1 of the first portions of the balloon are characterized by the following formula:

$$t_1 < t_2 \left(\frac{r_1 + R_1}{r_2 + R_2} \right)$$

2. The non-distensible balloon recited in Claim 1 wherein:

5 the transition wall extends from the end wall to the central wall and defines a height transition region wherein the transition wall extends from a first radius at the end wall to a second radius at the central wall, the height transition region having a first axial length; and

10 the transition wall defining a thickness transition region wherein the transition wall varies from a maximum thickness to a minimum thickness, the thickness transition region having a second axial length less than the first axial length.

3. The non-distensible balloon recited in Claim 2 wherein the second axial length of the thickness transition region is less than one half the first axial length of the height transition region.

4. The non-distensible balloon recited in Claim 2 wherein the thickness of the transition wall is constant between two different locations along the height transition region.

5. The non-distensible balloon recited in Claim 1 wherein the entire thickness transition region is disposed within an axial distance from the end zone equal to one half the axial length of the height transition region.

6. The non-distensible balloon recited in Claim 1 wherein the thickness t_1 of the first portions of the balloon is characterized by the following formula:

$$t_1 < \frac{1}{2} t_2 \left(\frac{r_1 + R_1}{r_2 + R_2} \right)$$

7. A method for making a non-distensible, inflatable balloon characterized by an end wall disposed in an end region of the balloon, a central wall disposed in a central region of the balloon, and a transition wall disposed
5 between the end wall and the central wall, the method comprising the steps of:

providing a blow mold having an end wall surface, a central wall surface, and a transition wall surface equivalent in shape to the external shape desired for the
10 respective end wall, central wall and transition wall of the balloon when the balloon is inflated;

inserting an elongate tube of material into the mold;

blow molding the material of the tube against the surface of the mold; and

15 reducing the average volume of material per unit axial length in the transition wall of the balloon to an amount less than the average volume of material per unit axial length in one of the end wall and central wall of the balloon.

8. The method recited in Claim 7 wherein:

prior to the inserting step the tube of material is characterized by an end zone providing the material to form the end wall of the balloon, a central zone providing the
5 material to form the central wall of the balloon, and a transition zone providing the material to form the transition wall of the balloon; and

during the reducing step the method further comprises the step of limiting the volume of the material per unit
10 axial length in the transition zone of the tube to an amount less than the volume of material per unit axial length in the one wall of the balloon.

9. The method recited in Claim 8 wherein prior to the inserting step the tube of material is provided with a cylindrical wall having a first thickness in the end zone, a second thickness in the transition zone, and a third
5 thickness in the central zone, and the second thickness is less than at least the third thickness.

10. The method recited in Claim 8 wherein during the blow molding step the method further comprises the steps of:
heating the tube of material; and
blowing a fluid into the tube against the surface of
5 the blow mold.

11. The method recited in Claim 10 wherein during the reducing step the method further comprises the steps of:
increasing the temperature of the material in the transition zone relative to the temperature of the material
5 in one of the end region and the central zone; and
axially stretching the tube to thin the transition wall of the balloon.

12. The method recited in Claim 11 wherein during the increasing step the method further comprises the step of cooling the central wall of the balloon.

13. The method recited in Claim 11 wherein during the increasing step the method further comprises the step of heating the transition wall of the balloon.

14. The method recited in Claim 11 wherein during the providing step the blow mold is characterized by a central wall formed of a non-heatconductive material and a transition wall formed of a heatconductive material, and
5 the increasing step includes the step of heating the mold to increase the temperature of the transition wall relative to the central wall of the mold.

15. A method for making a non-distensible balloon having a first wall characterized by a relatively small diameter, a second wall characterized by a relatively large diameter, and a third wall disposed between the first wall and the
5 second wall, the method comprising the steps of:
 providing a blow mold having an inner surface;
 inserting into the mold an elongate tube having a first zone associated with the first wall, a second zone associated with the second wall, and a third zone
10 associated with the third wall of the balloon;
 blowing a fluid into the tube to expand at least the second zone of the tube against the inner surface of the mold;
 heating the third wall of the balloon; and
15 stretching the third wall of the balloon axially to reduce the thickness of the third wall of the balloon.

16. The method recited in Claim 15 wherein during the heating step the method further comprises the steps of:
 providing a second mold with an inner surface;
 inserting at least the third wall of the balloon into
5 the second mold; and
 heating the second mold in order to heat the third wall of the balloon.

17. The method recite in Claim 16 wherein the step of heating the second mold further comprises the step of applying radiofrequency energy to the second mold to heat the second mold.

18. The method for thinning the wall of a balloon, comprising the steps of:

5 providing a non-distensible balloon having an elongate axis and characterized by a first relatively thick wall, a second relatively thin wall and a third wall disposed between the first and the second wall, the first wall, second wall and third wall having substantially the same volume of material per unit axial length of the balloon; and

10 increasing the average volume of material per unit axial length of the second wall relative to the third wall of the balloon.

19. The method recited in Claim 18 wherein:

5 the providing step includes the steps of providing a first balloon section including one of the first wall, second wall and third wall, and providing a second balloon section including one of the first wall, second wall and third wall; and

10 the increasing step includes the steps of inserting the second wall of the first balloon section into the second wall of the second balloon section, and bonding the second wall of the first balloon section to the second wall of the second balloon section.

20. The method recited in Claim 18 wherein the increasing step further comprises the steps of:

providing a sleeve of wall material;

5 inserting the sleeve over the second wall of the balloon; and

bonding the sleeve of the material to the second wall of the balloon to increase the volume of material per unit axial length of the second wall relative to the third wall of the balloon.

21. The method of Claim 18 wherein the increasing step includes the step of reducing the average volume of material per unit axial length of the third wall relative to the second wall of the balloon.

22. A method for making a non-distensible balloon having a first wall characterized by a relatively small diameter, a second wall characterized by a relatively large diameter, and a third wall disposed between the first wall and the second wall, the method comprising the steps of:

5 providing an elongate tube having a first zone associated with the first wall, second zone associated with the second wall and a third zone associated with the third wall of the balloon;

10 blowing a fluid into the tube to expand at least the second zone of the tube;

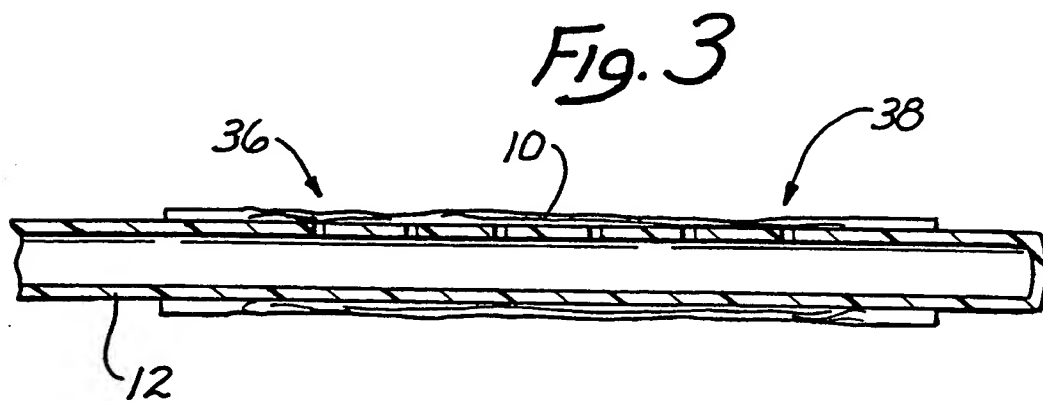
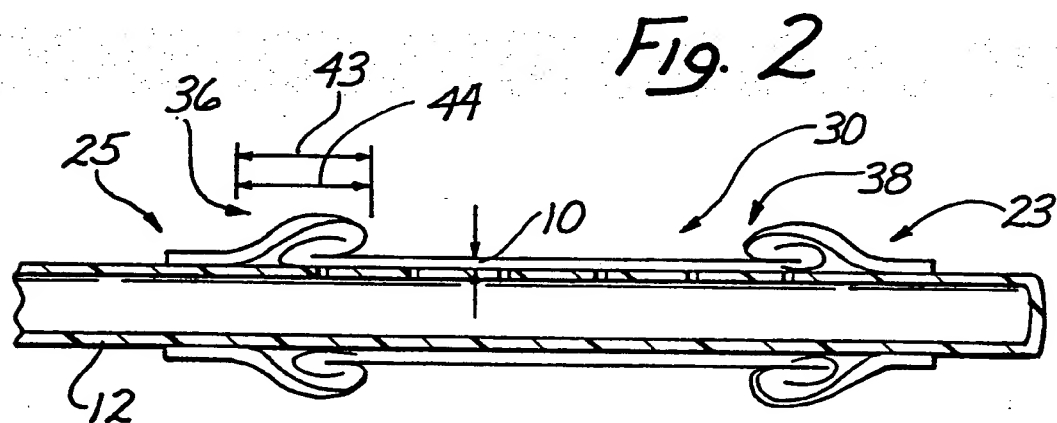
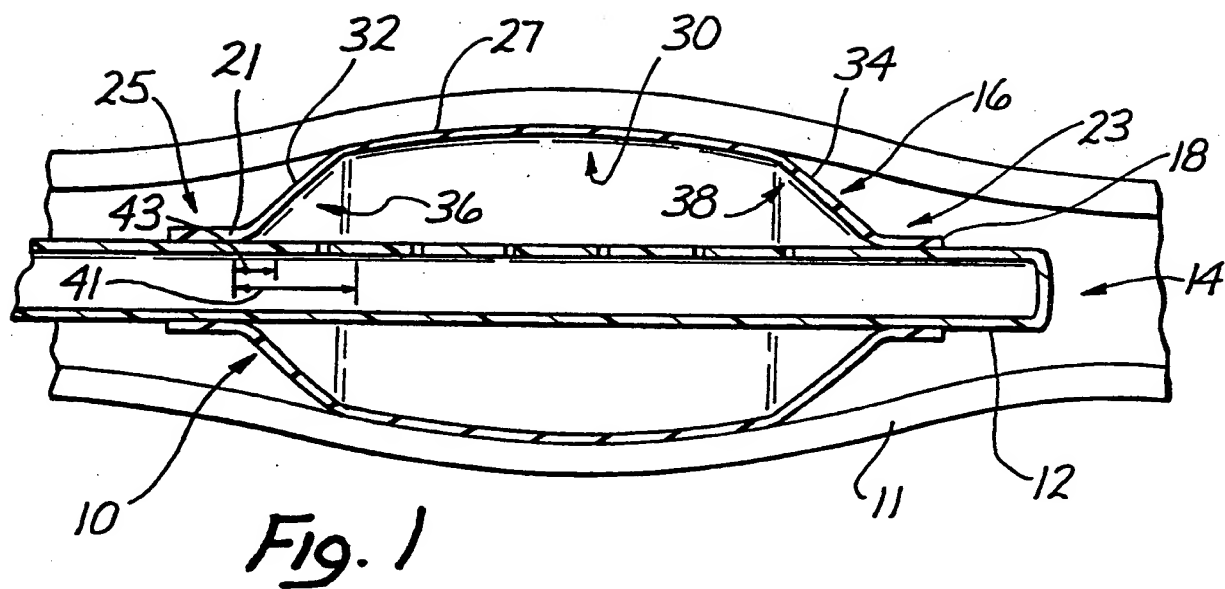
heating the third wall of the balloon; and

stretching the third wall of the balloon axially to reduce the thickness of the third wall of the balloon.

23. The method recited in Claim 22 wherein during the heating step, the method further comprises the step of heating the first wall of the balloon.

24. The method recited in Claim 23 wherein during the stretching step, the method further comprises the step of stretching the first wall of the balloon axially to reduce the thickness of the first wall of the balloon.

1 / 8



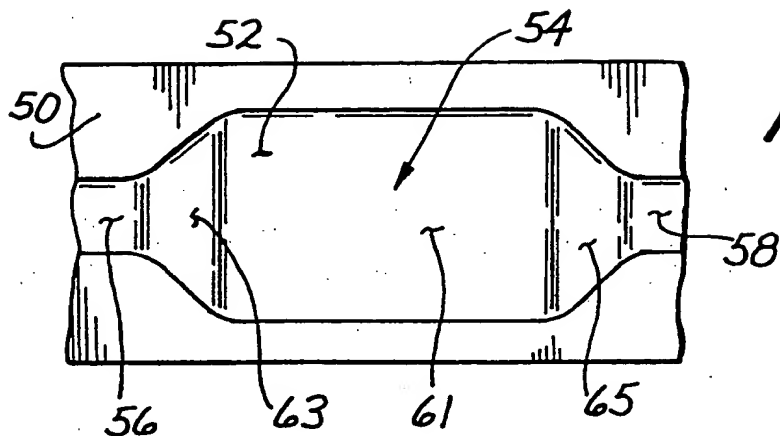


Fig. 4

Fig. 4a



Fig. 4b

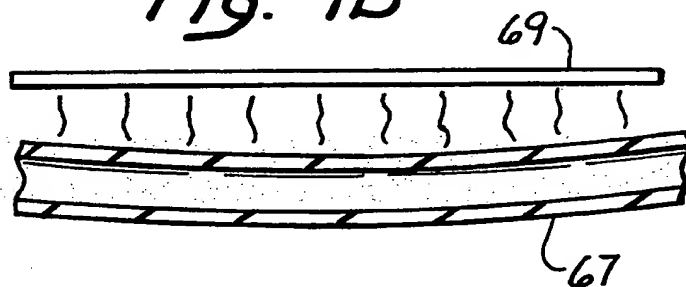


Fig. 4c

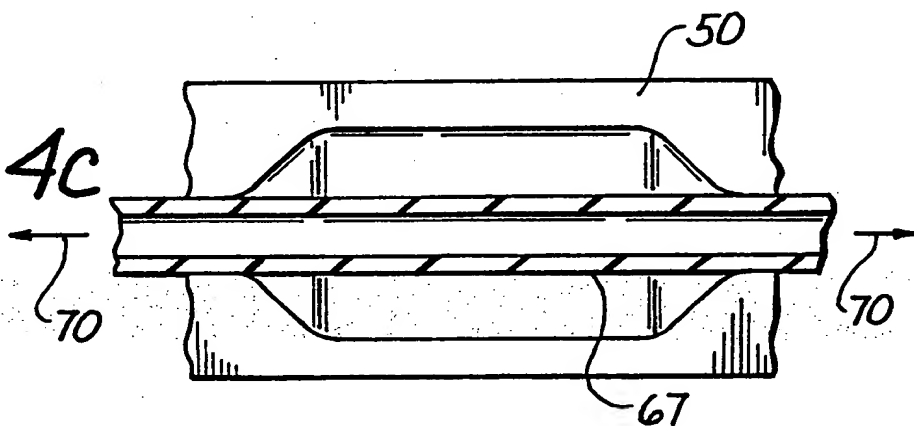
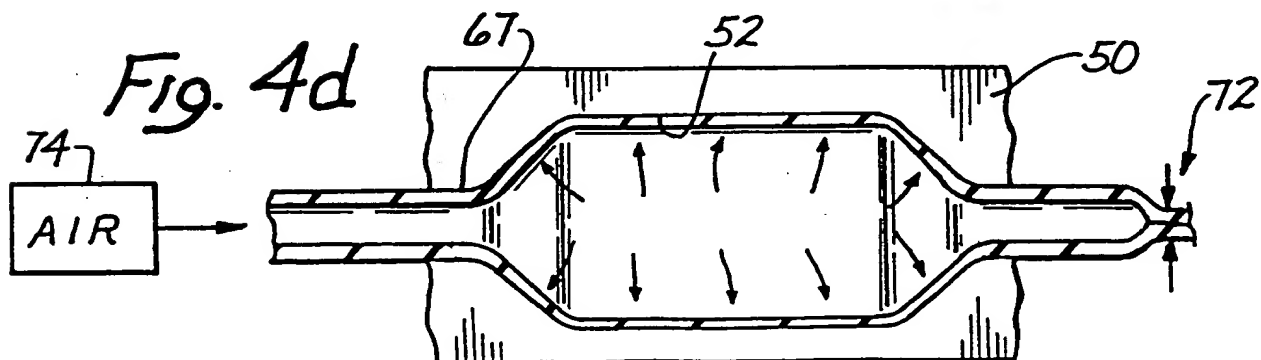
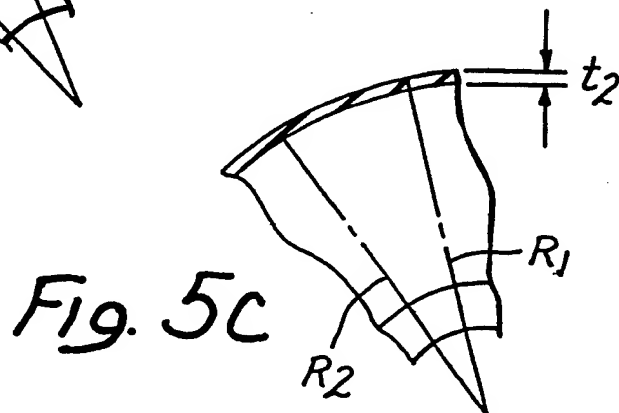
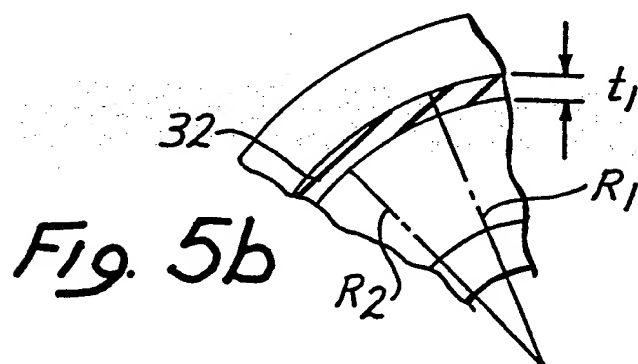
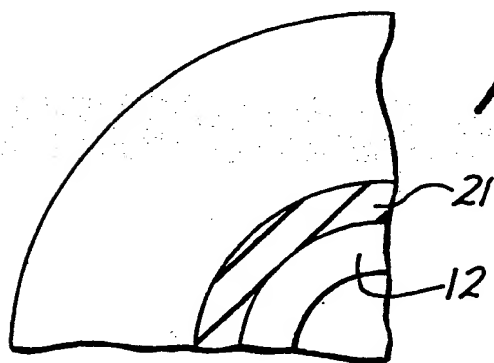
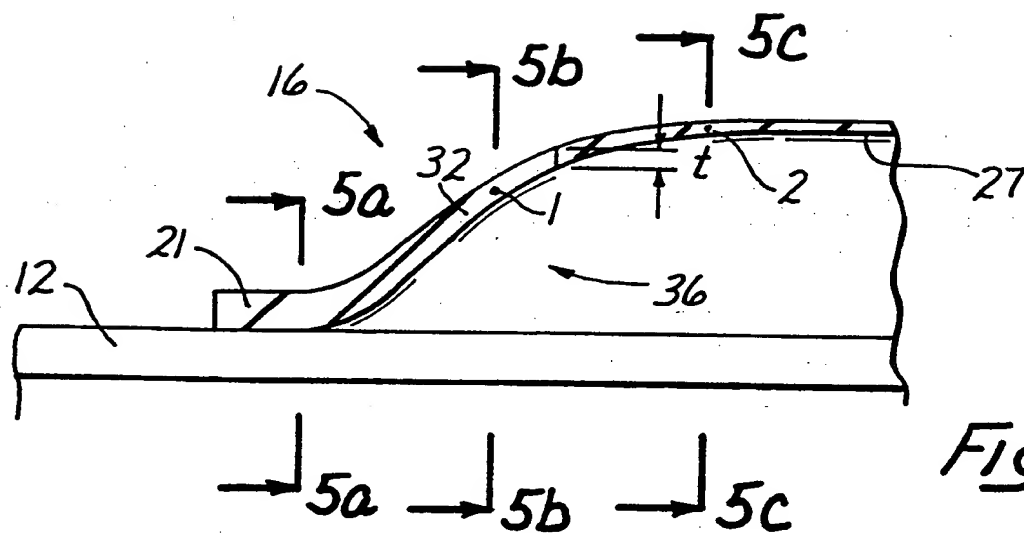


Fig. 4d





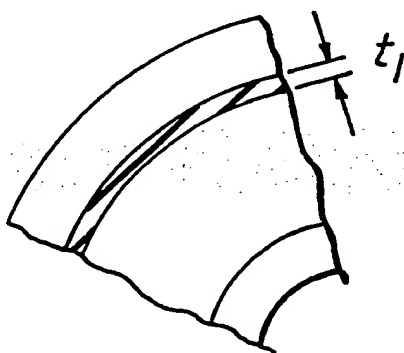
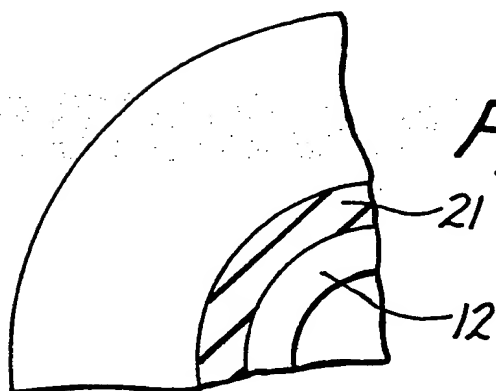
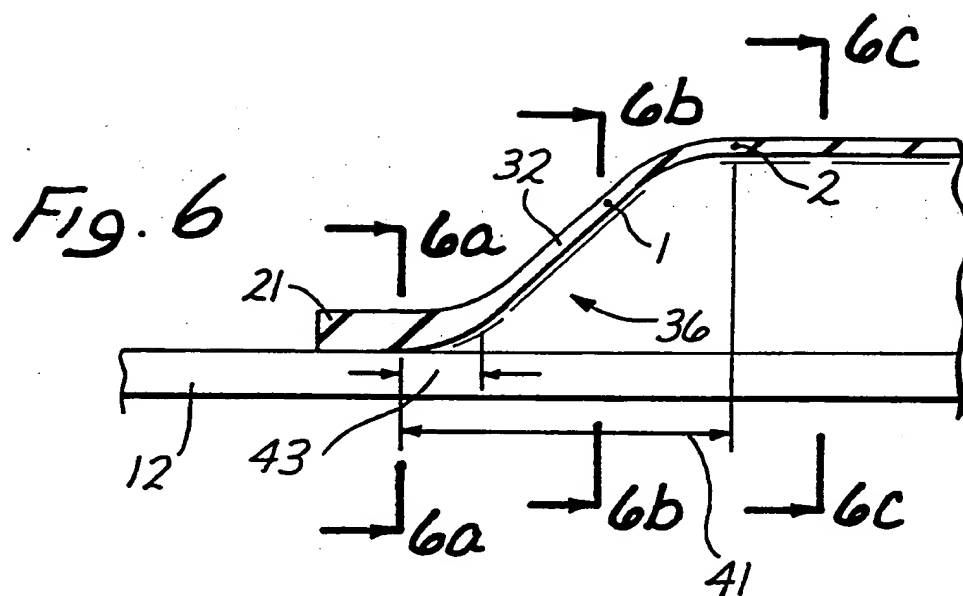


Fig. 6b

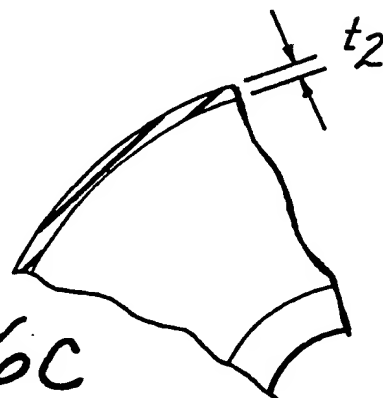
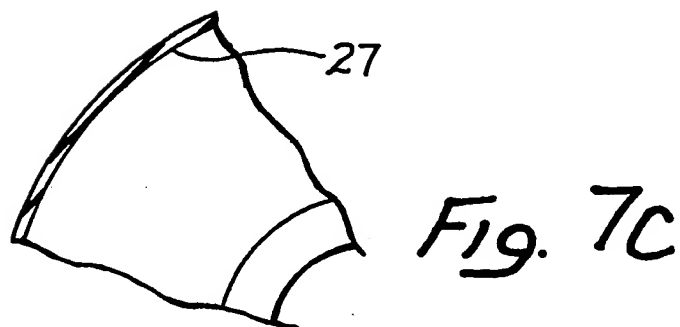
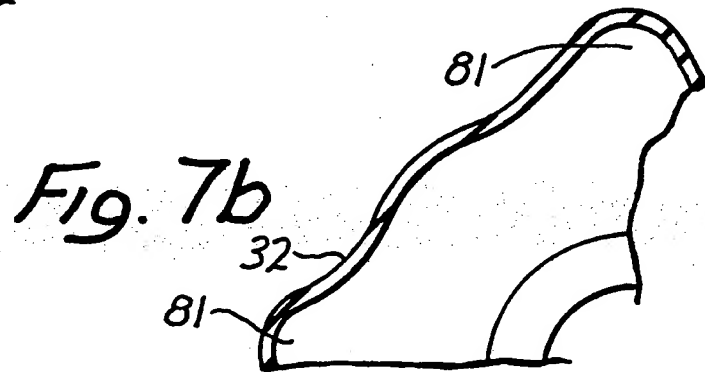
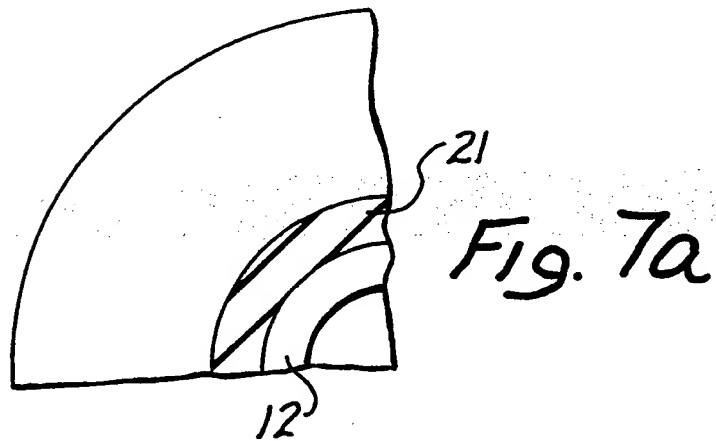
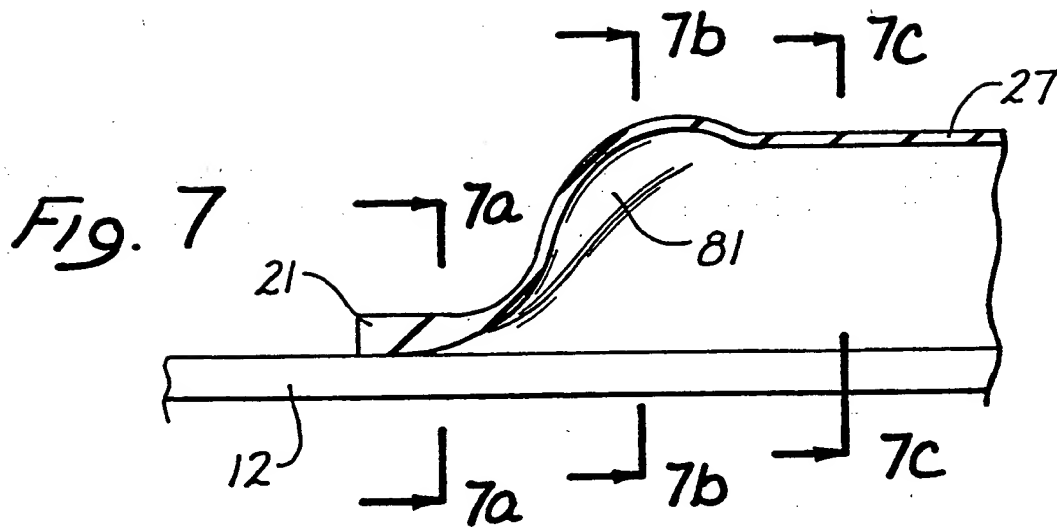


Fig. 6c



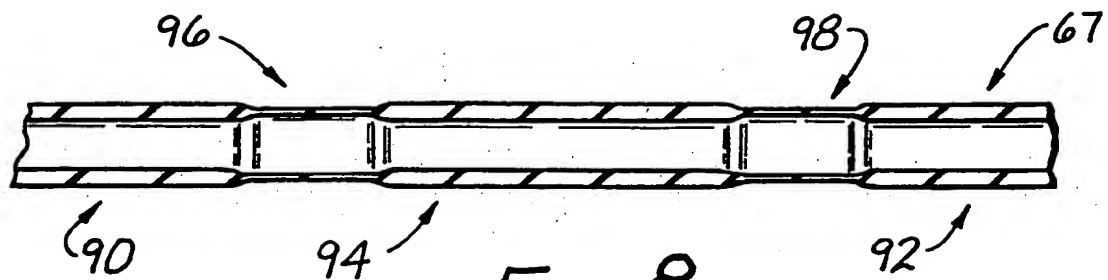


Fig. 8

Fig. 8a

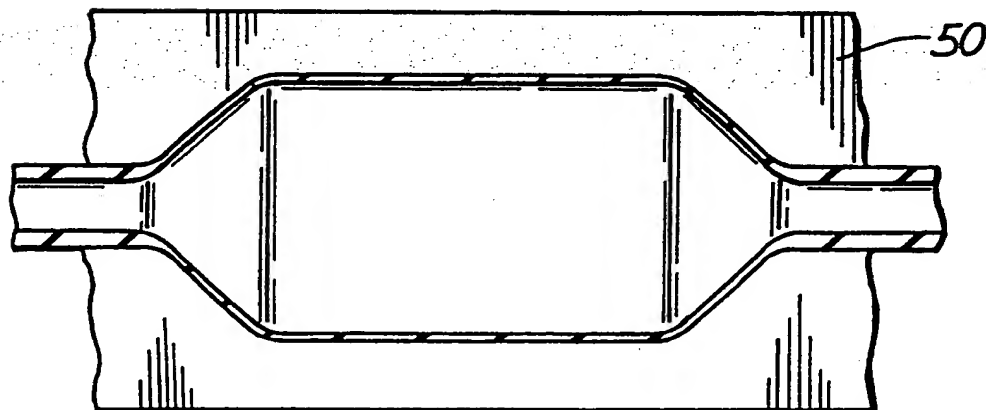
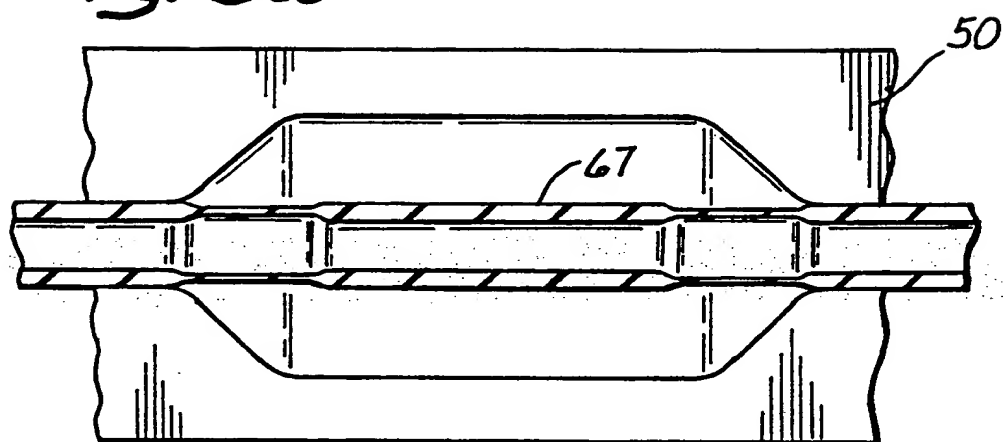


Fig. 8b

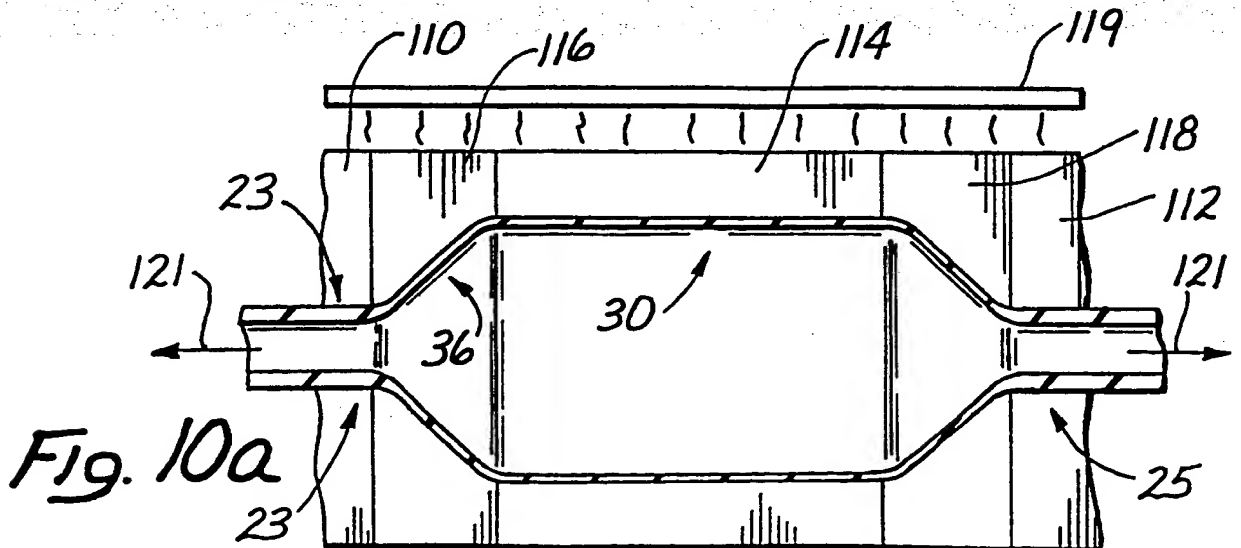
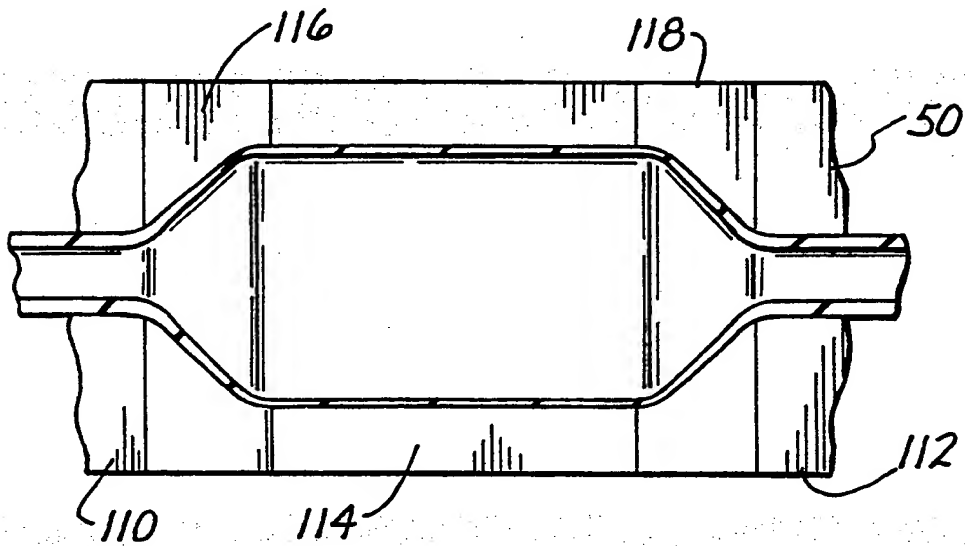
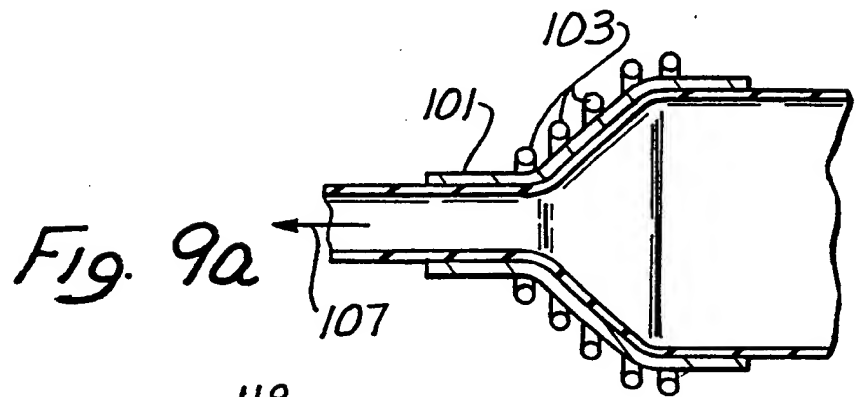
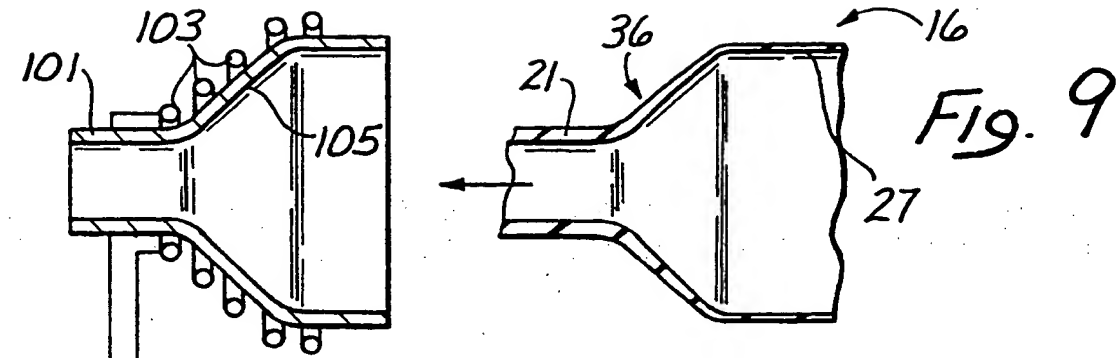


Fig. 11

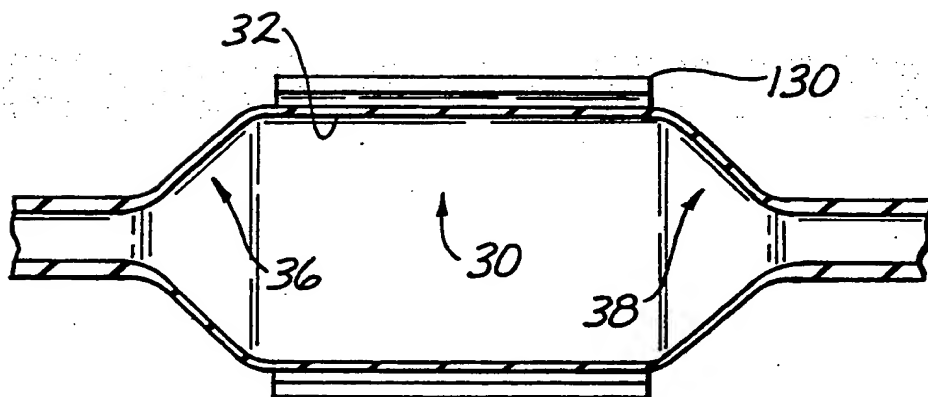
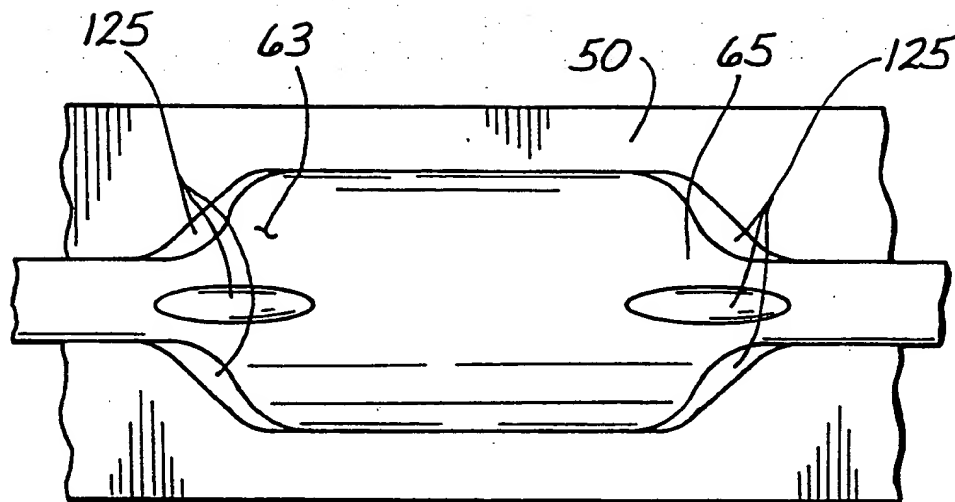


Fig. 12

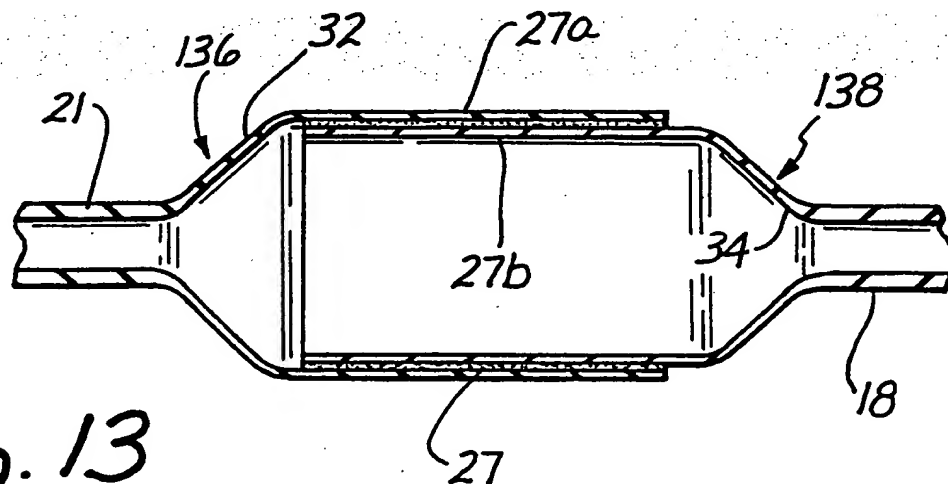
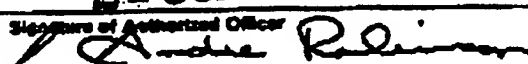


Fig. 13

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US92/00307

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) *		
According to International Patent Classification (IPC) or to both National Classification and IPC		
IPC(5). A61M 29/00	US CL. 604/96	
II. FIELDS SEARCHED		
Minimum Documentation Searched ?		
Classification System	Classification Symbols	
US	604/96-105 606/191, 192, 194, 195 264/129, 291, 292, 255, 305, 317, 512, 570, 573	
Documentation Searched other than Minimum Documentation to the extent that such Documents are included in the Fields Searched *		
III. DOCUMENTS CONSIDERED TO BE RELEVANT *		
Category *	Citation of Document, ** with indication, where appropriate, of the relevant passages †	Relevant to Claim No. ‡
X	US, A, 5,035,694 (KASPRZYK ET AL.), 30 July 1991, See figure 1.	1-6
A	US, A, 4,838,268 (KEITH ET AL.), 13 June 1989, See figure 3.	1-6
A	US, A, 4,952,357 (LUTENEUER), 28 August 1990, See entire document.	7-24
A	US, A, 4,963,313 (NODDIN ET AL.), 16 October 1990, See entire document.	7-24
<p>* Special categories of cited documents: ††</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"I" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"A" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
12 June 1992	24 JUN 1992	
International Searching Authority	Signature of Authorized Officer	
ISA/US	 William W. Lewis	

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☒ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☒ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.

This Page Blank (uspto)